



## Abstract

**Grant Number:** 1R01NR005075-01A1

**PI Name:** SIDANI, SOURAYA

**PI Email:** [s.sidani@utoronto.ca](mailto:s.sidani@utoronto.ca)

**PI Title:**

**Project Title:** ALTERNATIVE METHODS FOR CLINICAL RESEARCH

**Abstract:** *Clinical research is undertaken to evaluate the effectiveness of interventions with known efficacy or of community-based interventions requiring active client participation in their implementation. Conducting this type of clinical research while using the experimental design or randomized clinical trial (RCT) presents methodological and conceptual challenges. These challenges stem from differences between the RCT features and the reality of everyday practice. In practice, clients with different characteristics are cared for, are involved in treatment-related decisions, are not denied treatment if beneficial to them, and participate in the implementation of the intervention under the conditions of everyday life. Incorporating these features into the design of clinical research has been considered as threatening the validity of conclusions regarding the intervention effectiveness. Yet, it is needed to enhance the clinical utility of research findings. The purpose of this methodological study is to determine the influence of selected factors on the validity of a clinical study's conclusions. The specific aims are to determine the influence of clients' characteristics, research design or treatment options, treatment allocation procedures, and intervention components and dosage on clients' decision to enter treatment and outcome achievement. The theory-driven approach to intervention evaluation will guide the study. Different research designs, treatment options, and measurement methods will be used to obtain a comprehensive data set. This data set will permit the conduct of simulation-type analyses to identify the contribution of the methodological and conceptual factors to the validity of conclusions in clinical research.*

**Thesaurus Terms:**

*behavior therapy, clinical research, data collection methodology /evaluation, experimental*

*design, human therapy evaluation, method development, nursing intervention, nursing research, patient care management*  
*decision making, patient care planning, sleep disorder*  
*human subject, patient oriented research*

**Institution:** UNIVERSITY OF TORONTO  
215 HURON ST TORONTO  
TORONTO,

**Fiscal Year:** 2001

**Department:**

**Project Start:** 01-JUL-2001

**Project End:** 31-MAR-2006

**ICD:** NATIONAL INSTITUTE OF NURSING RESEARCH

**IRG:** NURS

